Submitted by
Joel Kurzman

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Generic Substitution of Brand Name Drug Tamper Resistant Formulations

- Legislation creating an exception to the generic substitution law for brand name drug tamper resistant formulations ("TRF") would unnecessarily increase state costs and complicate patient access to medicine.

- Current statute ensures that prescribers retain ultimate authority over whether or not a prescribed drug can be substituted with a generic equivalent. A prescriber's decision on this point is clearly articulated to the dispensing pharmacist on the face of the prescription. Layering on special requirements to the existing laws that would require pharmacists to obtain additional written and signed consent from the prescriber for certain prescription drug products would be redundant; prescribers *already* make the determination on whether or not generic substitution is permitted at the point of issuing a prescription.

- Redundant requirements that ultimately reaffirm prescribers' earlier choices will result in unnecessary delays in patient care. More often than not, pharmacists will be unable to reach prescribers who are otherwise busy treating patients, and will have to wait hours or days for a response. Such delays are both an inconvenience to patients and impediments to the timely delivery of patient care.

- Many third party insurers limit the number of brand name drugs they cover, though physicians are not always aware of a patient's formulary. Forcing the substitution of a medication that is not covered by an insurer would cause further complications and delays for the patient, including the possibility of waiting for a new script to be written. As of the end of 2011, there were only five (5) opioids that incorporate "tamper resistant technology" on the market. All five of these drugs are more expensive brand products, making it less likely that these drugs will be on many insurers' formularies.

- The type of legislation will bear a significant fiscal impact to the state, but has no proven commensurate public health benefit. In the state of Tennessee, the Tennessee Medicaid agency estimated that such legislation would increase state expenditures by $11,873,100 because no generics are currently available for any of the tamper resistant opioids.

- It bears noting that there is no empirical data that indicates TRF products actually deter abuse; unfortunately, addicts and abusers can easily find the means to circumvent this technology. Furthermore, the Food and Drug Administration has not made a determination that TRF products are any safer to a patient than an equivalent non-TRF drug.

413 North Lee Street
P.O. Box 1417-D49
Alexandria, Virginia
22313-1480

(703) 549-3001
Fax (703) 836-4869
www.nacds.org